

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-28. (Cancelled).

29. (Currently Amended) A method for assigning an individual having breast cancer to one of a plurality of categories in a clinical trial, comprising:

(a) classifying said individual as ER⁻, *BRCAl*[[,]]; ER⁻, sporadic; ER+, ER/AGE high; ER+, ER/AGE low, LN+; or ER+, ER/AGE low, LN⁻, wherein ER+ designates a high ER level and ER- designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said individual, and wherein LN+ designates a greater than 0 lymph nodes status in said individual and LN- designates a 0 lymph nodes status in said individual;

(b) determining for said individual a profile comprising measurements of the level levels of expression of at least two respective genes for which markers are listed in

(b1) Table 1 if said individual is classified as ER⁻, sporadic;

(b2) Table 2 if said individual is classified as ER⁻, *BRCAl*;

(b3) Table 3 if said individual is classified as ER+, ER/AGE high;

(b4) Table 4 if said individual is classified as ER+, ER/AGE low, LN+; or

(b5) Table 5 if said individual is classified as ER+, ER/AGE low, LN⁻;

(c) classifying determining, on a computer, said individual as having a good prognosis or a poor prognosis by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis template, wherein:

(i) said individual is classified as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or

(ii) said individual is classified as having a poor prognosis if said profile has a high similarity to said poor prognosis template, has a low similarity to said good prognosis template, or has a higher similarity to said poor prognosis template than to said good prognosis template, wherein said profile has a high similarity to said poor prognosis template

if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold,

wherein said good prognosis template comprises measurements of the levels of expression of said at least two respective genes that are representative of levels of expression of said at least two respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of the levels of expression of said at least two respective genes that are representative of levels of expression of said at least two respective genes in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a patient who has reoccurrence of metastases within a second period of time after initial diagnosis ~~whether said individual has a pattern of expression of said at least two genes that correlates with a good prognosis or a poor prognosis; and~~

(d) assigning said individual to one category in a clinical trial if said individual ~~has a~~ is classified as having a good prognosis, and assigning said individual to a second category in said clinical trial if said individual ~~has a~~ is classified as having a poor prognosis.

30-41. (Canceled)

42. (Currently Amended) A method for predicting a breast cancer patient as having a good prognosis or a poor prognosis, comprising:

(a) classifying said breast cancer patient into one of the following classes: (a1) ER⁻, sporadic; (a2) ER⁻, *BRCA1*; (a3) ER⁺, ER/AGE high; (a4) ER⁺, ER/AGE low, LN⁺; or (a5) ER⁺, ER/AGE low, LN⁻;

(b) determining a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes in a cell sample taken from said breast cancer patient, said ~~plurality of~~ respective genes comprising at least two of the genes for which markers are listed in

(b1) Table 1 if said breast cancer patient is classified as ER⁻, sporadic;

(b2) Table 2 if said breast cancer patient is classified as ER⁻, *BRCA1*;

(b3) Table 3 if said breast cancer patient is classified as ER⁺, ER/AGE high;

(b4) Table 4 if said breast cancer patient is classified as ER⁺, ER/AGE low, LN⁺; or

(b5) Table 5 if said breast cancer patient is classified as ER⁺, ER/AGE low, LN⁻; and

(c) comparing ~~classifying~~, on a computer, said profile to a good prognosis template and/or a poor prognosis template, wherein said good prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a patient who has reoccurrence of metastases within a second period of time after initial diagnosis; and

(d) classifying said breast cancer patient (i) as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or (ii) as having a poor prognosis if said profile has a high similarity to said poor prognosis template, has a low similarity to said good prognosis template, or has a higher similarity to said poor prognosis template than to said good prognosis template, wherein said profile has a high similarity to said poor prognosis template if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold, based on said profile of said plurality of genes;

wherein ER^{+} designates a high ER level and ER^{-} designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, and wherein LN^{+} designates a greater than 0 lymph nodes status in said patient and LN^{-} designates a 0 lymph nodes status in said patient.

43-44. (Canceled).

45. (Currently Amended) The method of ~~claim 43~~ claim 42, wherein said profile is an expression profile comprising measurements of said levels ~~a plurality of transcripts in a~~

~~sample derived from said patient~~, wherein said good prognosis template comprises measurements of ~~said plurality~~ levels of transcripts of said respective genes that are representative of expression levels of said transcripts in said plurality of good outcome patients, and wherein said poor prognosis template comprises measurements of ~~said plurality~~ levels of transcripts of said respective genes that are representative of expression levels of said transcripts in said plurality of poor outcome patients.

46-47. (Canceled).

48. (Currently amended) The method of claim 45, wherein measurement of each said transcript in said good prognosis template is an average of expression levels of said transcript in said plurality of good outcome patients, and wherein measurement of each said transcript in said poor prognosis template is an average of expression levels of said transcript in said plurality of poor outcome patients.

49-53. (Canceled)

54. (Previously presented) The method of claim 42, wherein said ER/AGE is classified as high if said ER level is greater than $c \cdot (AGE - d)$, and wherein said ER/AGE is classified as low if said ER level is equal to or less than $c \cdot (AGE - d)$, wherein c is a coefficient, AGE is the age of said patient, and d is an age threshold.

55-57. (Canceled).

58. (Previously presented) The method of claim 42, wherein said individual is ER⁻, sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

59. (Previously presented) The method of claim 42, wherein said individual is ER⁻, sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

60. (Previously presented) The method of claim 42, wherein said individual is ER⁻, *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

61. (Previously presented) The method of claim 42, wherein said individual is ER⁻, *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2.

62. (Original) The method of claim 42, wherein said individual is ER⁺, ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

63. (Original) The method of claim 42, wherein said individual is ER⁺, ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

64. (Original) The method of claim 42, wherein said individual is ER⁺, ER/AGE low, LN⁺, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

65. (Original) The method of claim 42, wherein said individual is ER⁺, ER/AGE low, LN⁺, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

66. (Previously presented) The method of claim 42, wherein said individual is ER⁺, ER/AGE low, LN⁻, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

67. (Previously presented) The method of claim 42, wherein said individual is ER⁺, ER/AGE low, LN⁻, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.

68-88. (Canceled).

89. (Currently Amended) A computer-implemented method for predicting a breast cancer patient as having a good prognosis or a poor prognosis, comprising:

classifying, on a computer, said patient as having a good prognosis or a poor prognosis based on a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes in a cell sample taken from said patient, said plurality of genes comprising at least two of the genes for which markers are listed in

(b1) Table 1 if said patient has been classified as ER⁻, sporadic;

(b2) Table 2 if said patient has been classified as ER⁻, *BRCAl*;

(b3) Table 3 if said patient has been classified as ER⁺, ER/AGE high;

(b4) Table 4 if said patient has been classified as ER⁺, ER/AGE low, LN⁺; or

(b5) Table 5 if said patient has been classified as ER⁺, ER/AGE low, LN⁻,

wherein ER⁺ designates a high ER level and ER⁻ designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, ~~and wherein~~ wherein LN⁺ designates a greater than 0 lymph nodes status in said patient and LN⁻ designates a 0 lymph nodes status in said patient,

wherein said classifying is carried out by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis template, wherein said good prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said

respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of good outcome patients, and said poor prognosis template comprises measurements of levels of transcripts of, or proteins encoded by, said respective genes in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a breast cancer patient who has reoccurrence of metastases within a second period of time after initial diagnosis, and wherein:

(i) said individual is classified as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or

(ii) said individual is classified as having a poor prognosis if said profile has a high similarity to said poor prognosis template, has a low similarity to said good prognosis template, or has a higher similarity to said poor prognosis template than to said good prognosis template, wherein said profile has a high similarity to said poor prognosis template if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold.

90. (Previously presented) A method for assigning a breast cancer patient to one of a plurality of categories in a clinical trial, comprising:

(a) determining if said person has a good prognosis or a poor prognosis using the method of claim 89; and

(b) assigning said patient to one category in a clinical trial if said patient is determined to have a good prognosis, and a different category if that patient is determined to have a poor prognosis.

91. (Canceled).

92. (Currently Amended) The method of ~~claim 91~~ claim 89, wherein said profile is an expression profile comprising measurements of said levels ~~a plurality~~ of transcripts in a

~~sample derived from said patient~~, wherein said good prognosis template comprises measurements of ~~said plurality~~ levels of transcripts of said respective genes that are representative of expression levels of said transcripts in said plurality of good outcome patients, and wherein said poor prognosis template comprises measurements of ~~said plurality~~ levels of transcripts of said respective genes that are representative of expression levels of said transcripts in said plurality of poor outcome patients.

93. (Currently Amended) The method of claim 92, wherein measurement of each said transcript in said good prognosis template is an average of expression levels of said transcript in said plurality of good outcome patients, and wherein measurement of each said transcript in said poor prognosis template is an average of expression levels of said transcript in said plurality of poor outcome patients.

94. (Previously presented) The method of claim 89, wherein said ER/AGE is classified as high if said ER level is greater than $c \cdot (AGE - d)$, and wherein said ER/AGE is classified as low if said ER level is equal to or less than $c \cdot (AGE - d)$, wherein c is a coefficient, AGE is the age of said patient, and d is an age threshold.

95. (Previously presented) The method of claim 89, wherein said individual has been classified as ER⁻, sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

96. (Previously presented) The method of claim 89, wherein said individual has been classified as ER⁻, sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

97. (Previously presented) The method of claim 89, wherein said individual has been classified as ER⁻, *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

98. (Previously presented) The method of claim 89, wherein said individual has been classified as ER⁻, *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2.

99. (Previously presented) The method of claim 89, wherein said individual has been classified as ER⁺, ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

100. (Previously presented) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

101. (Previously presented) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low, LN+, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

102. (Previously presented) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low, LN+, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

103. (Previously presented) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low, LN⁻, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

104. (Previously presented) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low, LN⁻, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.

105. (New) The method of claim 29, wherein said measurements of the levels of expression of said at least two respective genes in said good prognosis template is an average of expression levels of transcripts of said at least two respective genes in cell samples taken from said plurality of good outcome patients and wherein said measurements of the levels of expression of said at least two respective genes in said poor prognosis template is an average of expression levels of transcripts of said at least two respective genes in cell samples taken from said plurality of poor outcome patients.